UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

DWIGHT PETTY, Plaintiff, v. DEPUY ORTHOPAEDICS, INC.; DEPUY SYNTHES, INC.; DEPUY SYNTHES PRODUCTS, INC.; DEPUY SYNTHES SALES, INC.; d/b/a DEPUY SYNTHES JOINT RECONSTRUCTION; DEPUY INTERNATIONAL, LTD.; JOHNSON & JOHNSON SERVICES, INC.; JOHNSON & JOHNSON INTERNATIONAL, Inc.; JOHNSON & JOHNSON; MEDICAL DEVICE BUSINESS SERVICE, INC.; DEPUY INC.; DEPUY IRELAND UNLIMITED COMPANY; and DEPUY SYNTHES JOHNSON & JOHNSON IRELAND LTD Defendants.	**COMPLAINT AND JURY TRIAL DEMANDED**

Plaintiff Dwight Petty (hereinafter referred to as "Plaintiff"), by and through his undersigned attorneys, hereby files this Complaint and alleges against Defendants as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Dwight Petty is an adult resident of Shelby, North Carolina.

2. Defendant DePuy Orthopaedics, Inc. ("DePuy") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582 and regularly conducted business in the State of North Carolina by selling and distributing its products in North Carolina, with a registered office and principal place of business in North Carolina. DePuy is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

3. Defendant DePuy Synthes, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581.

4. Defendant DePuy Synthes Products, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 02767 and regularly conducted business in the State of North Carolina by selling and distributing its products in North Carolina. DSP is a division of DOI. DSP is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

5. Defendant DePuy Synthes Sales, Inc. d/b/a/ DePuy Synthes Joint Reconstruction ("DSS") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business located at 325 Paramount Drive, Raynham, Massachusetts 0276 and a registered agent address of CT Corporation: 160 Mine Lake Ct. Suite 200, Raleigh, NC 27615. Upon information and belief, DSS is a division and/or subsidiary of DePuy Orthopaedics, Inc. ("DOI"). DSS is a wholly owned subsidiary of Johnson & Johnson, a publicly traded company. DSS designs, makes, imports, distributes, sells and/or offers for sale total knee replacement prostheses, including the ATTUNE Device. DSS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events related to the ATTUNE Device.

6. Defendant DePuy International, Ltd. is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom.

7. Defendant Johnson & Johnson is and was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. Defendant Medical Device Business Services, Inc. ("Device Business Services") is and, at all times relevant, was a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, and regularly conducted business in the State of North Caorlina by selling and distributing its products in North Carolina, with a registered office and principal place of business in North Carolina. Device Business Services is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company.

9. Defendant DePuy, Inc. is and, at all times relevant, was a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. At all relevant times, DePuy, Inc. conducted regular and sustained business in North Carolina by selling and distributing its products in Carolina

10. DePuy, Inc., the parent company of DePuy Orthopaedics , Inc. was, at all relevant times, involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Upon information and belief, DePuy, Inc. participated in reviewing, investigating and/or responding to FDA adverse events and/or MAUDE reports related to the ATTUNE Device, and in the decision of whether to submit reports of ATTUNE failures to the FDA.

11. Defendant DePuy International, Ltd. ("DIL") is a public entity or corporation organized and existing under the laws of the United Kingdom, with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, LS11 8DT, United Kingdom, and at all times relevant was doing business within the United States. At all relevant times, DePuy International, Ltd. conducted regular and sustained business in North Carolina by selling and distributing its products in North Carolina. Depuy International makes, designs, imports, distributes, labels, sells and/or offers for sale certain total knee replacement prostheses, including the ATTUNE Device.

12. DePuy Ireland Unlimited Company ("DePuy Ireland") is a company and a citizen of Ireland with its principal place of business located at Loughbeg Industrial Estate, Loughbeg Ringaskiddy, County Cork, Ireland, and at all relevant times was doing business within the United States. At all relevant times, DePuy Ireland Unlimited Company conducted regular and sustained business in North Carolina by selling and distributing its products in North Carolina

13. At all times relevant, DePuy Ireland was involved in the business of designing, Manufacturing, distributing, selling, marketing. and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. DePuy Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and MAUDE reports concerning ATTUNE Device failures.

14. DePuy Synthes Johnson & Johnson Ireland Ltd. ("Synthes Ireland") is an entity doing business and organized in Ireland with its principal place of business located at Unit 2, Block 10, Blanchardstown Corporate Park, Dublin 15, Ireland, and at all relevant times was doing business within the. United States. At all relevant times, DePuy Synthes Johnson & Johnson Ireland Ltd. conducted regular and sustained business in North Carolina by selling and distributing its products in North Carolina. At all times relevant, Synthes Ireland was involved in the business of designing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly, through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Synthes Ireland had a role in the decision-making process and response of the Defendants, if any, related to the handling of adverse events and/or MAUDE reports concerning ATTUNE Device failures.

15. Defendant Johnson & Johnson International is and, at all times relevant, was a corporation organized and existing under the laws of the State of New Jersey with its principal

place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and regularly conducted business in the State of North Carolina by selling and distributing its products in North Carolina

16. Johnson & Johnson International is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson International participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports concerning the ATTUNE Device.

17. At all times material hereto, Defendant Johnson & Johnson ("J&J") is and was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of North Carolina by selling and distributing its products in North Carolina.

18. Johnson & Johnson, Depuy Inc.'s parent company, is and, at all relevant times, was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. Johnson & Johnson participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

19. At all times material hereto, Defendant Johnson & Johnson Services ("J&J Services") was a public entity or corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and at all relevant times was doing business in the State of North Carolina by selling and distributing its products in North Carolina. Johnson & Johnson Services is and, at all relevant times was, involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the ATTUNE Device, as well as monitoring and reporting adverse events associated with ATTUNE. J&J Services participated in the decision-making process and response, if any, related to adverse events and/or MAUDE reports related to ATTUNE Device failures.

20. At all relevant times, each Defendant was the representative, agent, employee or alter ego of the other Defendant, and in doing the things alleged herein was acting within the scope of its authority as such.

21. Jurisdiction is based upon diversity of citizenship and jurisdictional amount pursuant to 28 U.S.C. §§ 1332 and 1333.

22. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the Western District of North Carolina.

23. Pursuant to 28 U.S.C. § 1391, venue is proper in the United States District Court for the Western District of North Carolina.

24. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §1332 in that the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and this is an action by an individual Plaintiff against Defendants who are citizens of different states. Venue in the Western District of North Carolina is proper pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events giving rise to Plaintiff s claims occurred in the Western District of North Carolina, including the identification of the cause of the failure of the ATTUNE Device implanted in Plaintiff and the revision surgery to remove and replace the failed ATTUNE Device and resulting injury. Upon information and belief, Defendants regularly conducted business in the Western District of North Carolina. Defendants' commercial activities in the Western District of North Carolina include, but are not limited to, the advertising, promotion, marketing and sale of ATTUNE Devices.

BACKGROUND

25. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

26. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four small surfaces through a variety of motions essential to everyday life. It is also the joint most susceptible to arthritis.

27. With the increases in lifespan, people have begun to suffer pain and disability from knee joint arthritis at significant rates. Knee replacement technology can provide a solution to the pain and restore basic function to those implanted. The knee replacement implants designed and approved in the 1990s met the goals of reducing pain and restoring function with low failure rates.

28. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma. A TKA is ordinarily a successful orthopedic procedure with excellent clinical outcomes and survivorship.

29. In a TKA or TKR, physicians replace the joint surfaces and damaged bone and cartilage with artificial materials. The replacement redistributes weight and removes the tissue and/or bone causing inflammation, and thus reduces pain while improving the joint's function. Replacement requires a mechanical connection between the bones and the implant components.

30. DePuy Orthopaedics. Inc. was founded in 1895 and is purported to be a worldwide leader in the design and manufacture of orthopedic devices and supplies, including hip, knee extremity, cement and other products used in orthopedic procedures.

31. According to DePuy, the ATTUNE Device "builds on the LCS Complete Knee System and the SIGMA Rotating Platform Knee, both of which are also DePuy products.

32. DePuy introduced the P.F.C. Total Knee System in 1984 and the company introduced the DePuy Synthes P.F.C. SIGMA System (“SIGMA") in 1996.

33. The SIGMA was one of the most widely used TKAs worldwide, and DePuy quickly became one of the largest manufacturers of knee replacement devices in the United States. According to DePuy, the SIGMA Fixed Bearing Knee System has demonstrated excellent survivorship with 99.6% at 7 years.

34. In the 2000s, the company began investing in a new total knee replacement system, the ATTUNE project.

35. According to DePuy, the new ATTUNE project was an attempt to improve functional outcomes, provide more stability and simplify implantation of the contemporary total knee system.

36. The resulting ATTUNE total knee system purported to feature a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam. a tibial base which can be downsized or upsized two sizes versus the insert, novel patella tracking, lighter innovative instruments, and a new polyethylene formulation, according to DePuy. DePuy sought FDA clearance for the new ATTUNE Device through the "510(k)" process.

37. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be "substantially equivalent" to a product that has previously received FDA approval. The process requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance of introduction to the market. This is known as Premarket Notification─also called PMN or 510(k). This approval process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

38. By 2010, DePuy was ready to take the ATTUNE to market. In December 2010, DePuy Orthopaedics, Inc. received FDA clearance of the DePuy Attune™ Knee System under the "510k" notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee System. Consequently, Defendants received FDA approval with only very limited, if any, testing of the new ATTUNE Device.

39. The ATTUNE Device includes the Attune Tibial Base (510k Number K101433) ("ATTUNE tibial baseplate"), also called tibial tray, which, as compared to the SIGMA, included a design change to the keel, the surface texture and/or finish of the tibial baseplate and "combined with new technology to treat the underside of the implant,” among other changes.

40. The FDA cleared the following specific medical device components as part of the DePuy Attune™ Knee Total System:

a. The Attune™ Cruciate Retaining (CR) Femoral Component;
b. The Attune™ Fixed Bearing (113) Tibial Inserts;

c. The Attune™ Tibial Base, which is available in 10 sizes; and
d. The Attune™ Patellae.

41. In August 2011, DePuy Orthopaedics, Inc. received 510k clearance for the DePuy Attune Posterior Stabilized (PS) Femoral Components and PS Fixed Bearing inserts, which were additions to the existing DePuy Attune™ Knee System. These components are compatible with the ATTUNE fixed tibial bases. This product was referred to as the DePuy Attune™ PS Knee System.

42. The claims in this Complaint focus only on the ATTUNE Device as defined herein, which includes the DePuy Attune™ Knee System (including its component parts) and the DePuy Attune™ PS Knee System (including its component parts) (collectively referred to as "ATTUNE" and "ATTUNE Device" herein). The design and composition of the ATTUNE Device, especially the tibial baseplate, is defective and has failed, resulting in harm to Plaintiff, including, but not limited to, harm from the original March 20, 2017 DePuy Attune knee replacement implant and the May 11, 2020 revision surgery DePuy Attune implant.

43. In March of 2013, DePuy and the J&J Defendants introduced its ATTUNE Device, including procedures for implantation, to surgeons and consumers. On March 20, 2013, DePuy issued a press release widely introducing its "latest innovation in total knee replacement─the ATTUNE" Knee System─at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

44. According to the press release, the ATTUNE Device was "designed to provide better range of motion and address the unstable feeling some patients experience during everyday activities, such as stair descent and bending." According to DePuy, its "proprietary technologies include: . . . SOFCAM™ Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

45. The most notable improvement Defendants purported to make between the SIGMA and ATTUNE is the patented S-curve design of the femoral component. This feature, according to Defendants, conferred greater mid flexion stability as the implanted knee moves from extension to flexion because of the more gradual change in the femoral component radius of curvature. This design feature was also proposed to offer greater functional benefits and a greater range of movement as compared to other implants.

46. However the ATTUNE Device did not deliver on these promises, resulting in significantly higher failure rates than previous DePuy knee counterparts due to the debonding of the tibial baseplate. As a result, thousands of knee replacement patients implanted with ATTUNE Devices have had more expensive, more dangerous and less effective Total Knee Replacement surgeries, and many have required or will require expensive and dangerous knee revision surgery to remove and replace the defective ATTUNE Device.

47. Since the initial launch, Defendants have continued to expand the ATTUNE product line based on claims it would provide patients who were "expecting to maintain an active lifestyle" a more life-like knee. Defendants aggressively marketed the ATTUNE Device and became the dominant player in the knee market, upon information and belief, selling approximately 400,000 ATTUNE Devices worldwide.

48. The primary reason the ATTUNE Device fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the implant-cement interface. Mechanical loosening means that the attachment between the artificial knee and the existing bone has become loose. Such loosening will eventually result in failure of the device. Mechanical loosening has occurred at an unprecedented rate in patients implanted with an ATTUNE Device.

49. A loose artificial knee generally causes pain and wearing away of the bone. It can severely restrict a patient's daily activities as it can involve a severe physical and emotional burden for the patient.

50. Once the pain becomes unbearable or the individual loses function of the knee, another operation, often times called a "revision surgery," may be required to remove the knee implant and replace it with a new one.

51. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including limitations in range of motion, the ability to walk, and even death.

52. Beginning in 2013 and 2014, Defendants became aware of safety issues with the ATTUNE Device. These concerns were evidenced through failure reports submitted to and kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which houses medical device reports submitted to the FDA by reporters such as manufacturers, importers and device user facilities. Most related reports concern failures caused by ATTUNE Device design elements which caused loosening and/or debonding at the tibial baseplate cement/implant interface. These MAUDE reports detail an extremely high incidence of aseptic loosening at the tibial baseplate of the ATTUNE Device resulting in subsequent revision surgeries.

53. Upon information and belief, the FDA MAUDE database, as of June 2017, included approximately 1,400 reports of failures. Approximately 633 of these reports resulted in revision surgeries. By comparison, for the Persona knee replacement system, manufactured by Defendants, approximately 384,000 devices have been implanted, and the MAUDE database has a collection of only 183 reports of device failures with 64 of these resulting in revision surgeries.

54. On March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the first ATTUNE Knee revision system, which included the ATTUNE Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

55. Noticing the alarming rate of failure and subsequent revisions related to the ATTUNE Device, on March 10, 2016, DePuy Orthopaedics, Inc. submitted a Section 510(k) premarket notice of intent to market the "ATTUNE® Revision Knee System., which included a new stem, with added length and a keel for additional stability and recessed cement pockets intended to promote cement fixation. The stem of the ATTUNE® Revision Knee System was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

56. Without notifying consumers, doctors or patients, including Plaintiff and his Physicians, Defendants attempted to replace the original ATTUNE Fixed Base tibial baseplate

with a new tibial baseplate, also called a tibial tray, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate was an admission, or at the very least strong evidence, that the original ATTUNE Tibial Tray (baseplate) is defective and prone to failure. However, Defendants did not recall the defective tibial baseplate or inform consumers and surgeons about the dangers of its use.

57. Defendants requested FDA approval of the new tibial baseplate by application dated March 17, 2017 which was "prepared" by Defendants on March 16, 2016. The application requested clearance of a new tibial baseplate component as part of the Attune™ Knee Total System, which, upon information and belief, has been called the "Attune S+ Technology" ("ATTUNE S+") by Defendants. In particular. the application identified the design changes that were implemented with the ATTUNE S+, including a newly designed "keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or microblast finish.

58. The "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following: ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond.

59. Additionally, according to DePuy, the ATTUNE S+ tibial baseplate also features macro geometry and 45 degree undercut pockets designed to provide a macro-lock between the cement-implant interface. According to DePuy, the "ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested." See Depuy Synthes Powerpoint, "ATTUNE S+ Technology."

60. Defendants knew about the design defects and resulting failures with the original ATTUNE tibial baseplate long before the newly designed tibial baseplate (ATTUNE S+) was cleared in June of 2017, yet they failed to share this information with orthopedic surgeons using the Attune devices.

61. By March 16, 2016 or before, Defendants had apparently recognized the existence of high failure rates of the original ATTUNE tibial baseplate, identified the defects and/or mechanisms of failure associated with it, researched, and designed the new tibial tray/baseplate (Attune S+), conducted testing of this new tibial baseplate, as detailed in the application, and submitted the application to the FDA.

62. Although Defendants obviously knew about the high number of ATTUNE failures resulting in revision surgeries, they failed to warn surgeons, consumers and patients, and allowed the original, defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients, including Plaintiff and Plaintiff s physicians.

63. In fact, beginning in December 2016, DePuy began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE Devices were failing. Although DePuy decided to make a change, it did not inform the surgeons, consumers and/or patients. In responding

to the MAUDE reports involving failures of ATTUNE tibial baseplates, DePuy frequently provided the following "Manufacturer Narrative":

> a. The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance or other events within the quality system. (b)(4) has been undertaken to investigate further. ***The analysis. and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4).*** DePuy considers the investigation closed at this time. Should the additional information be received, the information will be reviewed and the investigation will be re-opened as necessary.

64. In January of 2017, the Journal of Arthroplasty published a study, led by Dr. Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled, Tibial Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee Arthroplasty Implants. The study reported that the thicker cobalt-chromium baseplate of the ATTUNE Device was associated with significantly more tibial bone loss.

65. During the AAOS Annual Meeting in March 2017, Dr. Todd Kelley. Assistant Professor of Orthopaedic Surgery at the University of Cincinnati College of Medicine, presented a poster entitled High Incidence of Stress Shielding and Radiolucent Lines with a Novel Total Knee System, which involved a study of the ATTUNE Device.

66. Prior to the study, the evaluators acknowledged that a relationship between stress shielding and bone resorption leading to aseptic loosening and implant failure existed. Consequently, the purpose of the study was to determine the incidence of radiographic stress shielding and radiolucent lines in the tibia and femur during the early postoperative period following the implant of an ATTUNE Device.

67. As part of this study, 164 patients underwent a total knee replacement with the ATTUNE Device between February 2013 and February 2015. The mean length of the postoperative radiographic follow up was eight months. For all evaluators in the study, stress shielding was most frequently identified at the same three zones, with the highest incidence at "tibial AP zone 1," which was the medial baseplate. The incidence rate at this zone was 39.0%-48.5%.

68. The findings also demonstrated that the mean incidence rate of stress shielding at the tibial AP zone 1 among all evaluators was 43.1% and the mean incidence rate of radiolucent lines observed at this zone was 12.0%. These rates far exceed the rate expected in the post-surgery period.

69. In 2017, the rate of failures associated with the ATTUNE Device due to debonding of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthoplasty System at Implant-Cement Interface. The article presented compelling evidence that the design and/or composition of the ATTUNE Device, and particularly the tibial baseplate

component, contribute greatly to debonding at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

70. The authors' intraoperative findings identified freely mobile tibial baseplates with loosening occurring at the implant-cement interface. In all tibial baseplate failures in the study, the tibial component had debonded and was easily separated from the cement mantle, while all the cement was strongly adherent to the tibial bone. On the femoral side, however, the cement was strongly adherent to the implant surface in all cases. The mean time to revision for those ATTUNE Devices involved in the study was 19 months.

71. The authors of the Bonutti study concluded that high rates of ATTUNE failures due to debonding at the tibial-cement interface could be caused by a combination of factors, including the increased constraint of the ATTUNE's tibial polyethylene component; rounded edges and reduced cement pockets necessary for cement interdigitation in the tibia, as compared to the DePuy SIGMA; reduced keel rotational flanges and/or stabilizers on the keel; and insufficient surface roughness of the tibial baseplate component.

72. In December 2021 an article published in the Cureus Journal of Medical Science was written by Dr. John D. Murphy and colleagues, titled: Early Asteptic Failure of the Tibial Component-Cement Interface in Attune Total knee Arthroplasty: A Report of Three Cases. The article presented three separate cases of aseptic loosing and the causes of such loosening.

73. The authors found that the ATTINE Device has a high rate of aseptic failures. They concluded that the ATTUNE tibial baseplate had a lack of porous coating or grit plasting which resulted in persistent loosening of tibial component causing the implant failure.

74. Despite Defendants' claim that the ATTUNE Device would be easier to implant, after being notified of premature tibial baseplate failures, Defendants began blaming implanting surgeons and their surgical technique for the failures of the ATTUNE tibial baseplates rather than the ATTUNE's defects, which Defendants knew existed long ago.

75. According to Defendants, the ATTUNE Device produces better stability of the knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative flexibility and efficiency, and implant longevity. Defendants aggressively marketed the ATTUNE based on these assertions. Despite these claims, large numbers of revision cases appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.

76. Patients were promised they could recover faster, and engage in more active lifestyles. Contrary to Defendant’s representations, however, the ATTUNE Device is prone to failure, causing patients to experience additional pain and injury.

77. Defendants designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the sale and distribution of medical devices, and by these activities, caused ATTUNE Devices to be placed into the stream of commerce throughout the United States and within North Carolina.

78. Defendants actively and aggressively marketed to doctors and the public that the ATTUNE Devices were safe and effective total knee prostheses.

79. From the time that Defendants first began selling ATTUNE Devices, the product labeling and product information for the ATTUNE Device failed to contain adequate information, instructions, and warnings concerning the increased risk that the ATTUNE Device fails at an extremely high rate.

80. Despite Defendants' knowledge of the serious injuries associated with the use of the ATTUNE Device, Defendants continued to engage in marketing and advertising programs which falsely and deceptively create the perception that the ATTUNE Device is safe.

81. Upon information and belief, Defendants downplayed the health risks associated with the ATTUNE Device through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Plaintiff's surgeons, and potential users of the ATTUNE Device by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE.

82. Based on the design changes made to the original ATTUNE tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their premarketing and post marketing analysis, knew or should have known that the ATTUNE Device was prone to fail. Plaintiff alleges that the ATTUNE Device is defective and unreasonably dangerous.

PLAINTIFF'S HISTORY WITH ATTUNE TOTAL KNEE REPLACEMENT

83. On or about March 20, 2017, Plaintiff, underwent a left-sided total knee replacement surgery at Orthocarolina in North Carolina. Plaintiff was implanted with a DePuy ATTUNE Device, including, but not limited to a fixed tibial insert and a fixed tibial baseplate, posterior stabilized femur, which was designed, manufactured, distributed, labeled, marketed, and sold throughout the United States by the Defendants. The ATTUNE Device was purchased by Plaintiff.

84. After the ATTUNE Device was implanted, Plaintiff began experiencing persistent pain, for which he was followed and given pain medication by his treating physicians. In 2020 his treating physician referred him to the implanting physician for further evaluation. The implanting physician ordered a radiograph of Plaintiff's left knee. The implanting physician scheduled left knee revision surgery, which was performed at Carolina Orthopedic & Sports Medicine center, P.A. on or about May 12, 2020 and revealed that the tibial portion of the implant had loosened.

85. Thereupon a left total knee revision, involving revision of the tibial and femoral components, was performed. On information and belief, the same defective make and model DePuy ATTUNE Device that was implanted on March 20, 2017 was implanted in the May 12, 2020 revision surgery.

86. Plaintiff continues to have pain in his left knee and continues to require medical treatment on the left knee even after having the revision surgery.

87. Plaintiff nor his physicians became aware of the aseptic loosening until the actual procedure was performed on May 2020. During the revision surgery is when the doctor's noticed the femur was tamped on and it was grossly loose and was de-bonded from the cement.

88. Prior to the surgery, Neither Plaintiff nor his physicians were aware, by warning or otherwise, of the defects in the ATTUNE Device.

89. As a direct and proximate result of the Defendants' placing the defective ATTUNE Device in the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: costly, painful, and dangerous revision surgery; past, present and future physical and mental pain and suffering and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, dependence on and addiction to pain medication, economic damages and other related damages. In addition, Plaintiff is now at increased risk of needing further medical treatment and potential surgeries because of the damage done by the defective ATTUNE knee device.

COUNT 1: NEGLIGENCE

90. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

91. At all times herein mentioned, the Attune was researched, designed, manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was unreasonably dangerous to consumers such as Plaintiff.

92. The Attune device was expected to and did reach the usual consumers, handlers, and persons, including Plaintiff, coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed and marketed by Defendants.

93. At all times relevant herein, Attune was researched, designed, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was in an unsafe, defective, and unreasonably dangerous condition when it left Defendants' possession and entered the stream of commerce. As designer, manufacturer, and/or seller of such medical devices, Defendants had a duty to exercise reasonable and ordinary care in the design, testing, manufacture, marketing, distribution, approval, and sale of the Attune.

94. Defendants had a continuing duty to the medical community and public, including Plaintiff and his physicians, arising from designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, selling, assuring quality, and controlling quality of the Attune.

95. Defendants failed to exercise ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, distributing, approving, and selling of the Attune into interstate commerce in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, including the loosening and

debonding at the tibial plate, thereby breaching their duty to consumers, including Plaintiff

96. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the Attune Device. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Attune Device in a way as to make the risk of harm or injury outweigh any therapeutic benefits.

97. The negligence of Defendants, their agents, servants, and/or employees, included, but was not limited to, the following acts and/or omissions:

(a) Negligently designing Attune in a manner which was dangerous to those individuals who had the device surgically implanted;

(b) Designing, manufacturing, producing, creating and/or promoting the Attune without adequately, sufficiently, or thoroughly testing it;

(c) Failing to adequately and correctly warn Plaintiff and his physicians, hospitals, and/or healthcare providers of the dangers of the Attune;

(d) Failing to recall their dangerous and defective Attune at the earliest date that it became known that the device was, in fact, dangerous and defective;

(e) Advertising and/or marketing the use of the Attune despite the fact that Defendants knew or should have known of its defects;

(f) Representing that the Attune was safe for its intended purpose when, in fact, it was unsafe;

(g) Manufacturing the Attune in a manner which was dangerous to those individuals who had it implanted; and

(h) Under-reporting, underestimating, and/or downplaying the serious danger of Attune.

98. Upon information and belief, Defendants continued to market, manufacture, distribute and/or sell the DePuy Attune device to consumers, including Plaintiff, despite the fact that Defendants knew or should have known that the DePuy Attune caused unreasonably dangerous defects, including a defective viscosity design leading to early debonding and early failures.

99. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injuries as a result of Defendants' failure to exercise ordinary care as described above.

100. At all material times, Defendants knew of the defective nature of the Attune device as set forth herein, and continued to design, manufacture, market and sell it so as to maximize sales and profits at the expense of public health and safety, and as such Defendants' conduct exhibited a wanton and reckless disregard for human life.

101. As a direct and proximate result of one or more of the forgoing wrongful acts or omissions by Defendants, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to his normal affairs and duties for an indefinite period of time.

102. Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the Court deems proper, as well as a trial by jury of all issues to be tried.

CLAIM II: GROSS NEGLIGENCE

103. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

104. Defendants knew in at least 2016 that the Attune device was defective.

105. Defendants failed to notify its consumers, physicians, doctors and other stakeholders of the defective nature of the device.

106. Defendants allowed doctors and hospitals and other medical personnel to continue to implant the defective device into patients, like Plaintiff, after they were placed on notice of Attune defects.

107. Defendants continued to receive payments from patients and insurance companies to purchase the defective product without informing them of the products' defects and the damage its defects could cause its users.

108. Specifically, the acts and omissions of Defendants described herein consisted of oppression, fraud, and/or malice, as those terms are defined under North Carolina law, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

109. Defendants misled both the medical community and the public, including Plaintiff and/or his physicians, by making false representations about the safety and effectiveness of the Attune device and by failing to provide adequate instructions and training concerning its use.

110. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Attune despite available information demonstrating that the device could fail when used according to its ordinary and intended use.

111. Defendants were or should have been in possession of evidence demonstrating that Attune could lead to mechanical loosening and early revision surgeries, causing a multitude of potential injuries. Nevertheless, Defendants continued to market Attune by providing false

and misleading information with regard to its safety and effectiveness.

112. Defendants failed to provide warnings that would have dissuaded health care professionals from using Attune, thus preventing health care professionals, including Plaintiff and his medical providers from weighing the true risks against the benefits of using Attune.

113. Defendants' acts were willful and wanton and were done with recklessness and disregard for human life.

114. Consequently, Defendants are liable for compensatory damages and punitive damages in an amount to be determined by the jury and attorneys fees and costs as provided by law.

CLAIM III: BREACH OF EXPRESS WARRANTY

115. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

116. Defendants made representations of fact or promises to consumers, including Plaintiff and/or his physicians, regarding the character or quality of Attune including, but not limited to, statements that the Attune is safe and effective.

117. Attune was defective in that when it left the Defendants' possession it did not conform to Defendants' representations and did not conform to Plaintiff's expectations.

118. Plaintiff and/or his physicians justifiably relied on Defendants' representations regarding the safety of the Attune and Defendants' representations became part of the basis of the bargain.

119. As a direct and proximate result of Defendants' placement of the defective Attune Device into the stream of commerce and Plaintiff's use of the defective Attune Device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants and/or Defendants' failure to comply with federal requirements, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

120. Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages.

CLAIM IV: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

121. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

122. At the time Defendants marketed, sold, and/or distributed the ATTUNE, it knew that the knee device was intended for human use.

123. At the time Defendants marketed, sold, and/or distributed the ATTUNE, Plaintiff was a foreseeable user of the device.

124. At the time Defendants marketed, sold, and/or distributed the ATTUNE, it impliedly warranted that the ATTUNE, including all of its component parts, was safe and merchantable for its intended use. Defendants warranted that the implanted ATTUNE was a good that at a minimum:

a. Would pass without objection in the trade under the contract description;
b. Was fit for the ordinary purposes for which such goods are used;
c. Would run, within the variations permitted by the agreement, of even kind, quality, and quantity within each unit and among all units involved; and/or,
d. Conformed to the promises or affirmations of fact made on the container or label if any.

125. Defendants, when they sold the implanted ATTUNE, breached the foregoing implied warranty of merchantability.

126. Plaintiff and his implanting surgeon reasonably relied upon the representations that the ATTUNE was of merchantable quality and safe for its intended uses.

127. Plaintiff used the ATTUNE for its intended purpose.

128. Contrary to the implied warranties, at the time Defendants marketed, sold and/or distributed the ATTUNE, it was not of merchantable quality or safe for their intended use described above.

129. As a direct and proximate result of one or more of the forgoing wrongful acts or omissions by Defendants, Plaintiff was caused to suffer and sustain injuries of a permanent nature; to endure pain and suffering in body and mind; to expend money for medical care in the past and in the future; furthermore, Plaintiff was unable to and will in the future be unable to attend to his normal affairs and duties for an indefinite period of time.

CLAIM V: UNFAIR AND DECEPTIVE TRADE PRACTICE -MISREPRESENTATION

130. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

131. Defendants sells the Attune Devices that are implanted as TKR and are advertised, marketed and sold throughout North Carolina.

132. Defendants made representations of fact or promises to consumers, including Plaintiff and/or his physicians, regarding the character or quality of Attune including, but not limited to, statements that the Attune is safe and effective.

133. Attune was defective in that when it left the Defendants' possession it did not conform to Defendants' representations and did not conform to Plaintiff's expectations.

134. Defendants knew that the product did not conform to Defendant' representation when it was placed in the marker.

135. Defendants knew the Attune Device was defective when it went to market.

136. Defendants failed to give notice or warnings to consumers like Plaintiff or their medical providers of the defective nature of the Attune Device.

137. Defendants' conduct were immoral, unethical and substantially injurious to consumers that constituted and unfair and deceptive trade practice.

138. Defendants' conduct were a direct and proximate cause of Plaintiff's injuries and continued medical care.

139. Defendants' conduct and practices occurred in commerce, were unfair and deceptive trade practices and entitle Plaintiff to treble their actual damages and recover attorney's fees, pursuant to the provisions of N.C.G.S. 75.1, *et seq.* and 75-16.1, *et seq*.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, individually and collectively, jointly and severally, as follows:

1. Trial by jury;

2. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00), in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present;

3. Compensation for economic and non-economic damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, and pain and suffering;

4. Judgment against Defendants for their Unfair and Deceptive Trade Practices against Plaintiff in an amount equal to treble the compensatory damages, and that Defendants be ordered to Plaintiff's attorney fees pursuant to N.C. Gen. Stat. 75-16.1.

5. For reasonable attorneys' fees and costs;

6. For pre-judgment interest; and

7. For such further and other relief the Court deems just and equitable.

THIS the 17th day of April 2023.

s/Lawrence Wooden
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